

54. A method for extracting an analyte from a fluid sample, the method comprising the steps of:
- a) introducing the sample into a cartridge having:
 - i) a lysing region for lysing sample components to release the analyte therefrom, wherein the lysing region contains solid phase material for capturing the sample components as the sample flows through the lysing region; and
 - ii) an analyte capture region containing capture material for capturing the analyte;
 - b) forcing the sample to flow through the lysing region to capture the sample components with the solid phase material;
 - c) lysing the sample components in the lysing region to produce a lysate containing the analyte;
 - d) forcing the lysate to flow through the capture region, thereby capturing the analyte with the capture material, and
 - e) eluting the analyte from the capture region.
55. The method of claim 54, wherein the cartridge further includes a reaction chamber, and the method further comprises the steps of:
- i) forcing the eluted analyte to flow into the reaction chamber;
 - ii) chemically reacting the analyte in the reaction chamber; and
 - iii) detecting a reaction product.
56. The method of claim 55, wherein the analyte comprises nucleic acid, and wherein the steps of chemically reacting the analyte and detecting the reaction product comprise amplifying the nucleic acid and detecting the amplified nucleic acid.
57. The method of claim 55, wherein the chemical reaction requires temperature control of the reaction chamber, the portion of the cartridge defining the reaction

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chamber protrudes from the rest of the cartridge body, and the method further comprises the steps of inserting the reaction chamber into a thermal sleeve and heating or cooling the reaction chamber according to a time/temperature profile.

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58. The method of claim 55, wherein the cartridge further includes a reagent chamber containing dried or lyophilized reagents, and the method further comprises the step of mixing the eluted analyte with the reagents in the reagent chamber prior to forcing the analyte to flow into the reaction chamber.
59. The method of claim 54, further comprising the steps of:
- i) forcing the eluted analyte to flow into a reaction vessel coupled to the cartridge;
 - ii) chemically reacting the analyte in the reaction vessel; and
 - iii) detecting a reaction product.
60. The method of claim 59, wherein the analyte comprises nucleic acid, and wherein the steps of chemically reacting the analyte and detecting the reaction product comprise amplifying the nucleic acid and detecting the amplified nucleic acid.
61. The method of claim 59, wherein the chemical reaction requires temperature control of the reaction vessel, and the method further comprises the steps of inserting the vessel into a thermal sleeve and heating or cooling the vessel according to a time/temperature profile.
62. The method of claim 59, wherein the cartridge further includes a reagent chamber containing dried or lyophilized reagents, and the method further comprises the step of mixing the eluted analyte with the reagents in the reagent chamber prior to forcing the analyte to flow into the reaction vessel.

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63. The method of claim 54, wherein the step of lysing the sample components comprises transferring ultrasonic energy to the lysing region using an ultrasonic transducer coupled to a wall of the lysing region.
64. The method of claim 63, wherein the lysing region comprises a lysing chamber, and the solid phase material comprises at least one membrane or filter in the lysing chamber for capturing the sample components.
65. The method of claim 64, wherein the step of lysing the sample components further comprises agitating particles or beads in the lysing chamber to rupture the sample components.
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66. The method of claim 63, further comprising the step of placing a lysis buffer in the lysing region, the lysis buffer containing a lysing reagent.
67. The method of claim 63, wherein the transducer comprises an ultrasonic horn for contacting the wall.
68. The method of claim 54, wherein the capture region comprises a channel or chamber containing the capture material, and the method further comprises the step of forcing a wash solution to flow through the capture region after the step of forcing the lysate to flow through the capture region and prior to eluting the analyte from the capture region.
69. The method of claim 54, wherein the solid phase material in the lysing region is selected from the group consisting of at least one filter, at least one membrane, beads, fiber, glass wool, filter paper, polymers, and gel.

70. The method of claim 54, wherein the capture region comprises a channel or chamber containing the capture material, and wherein the capture material comprises at least one solid support selected from the group consisting of filters, membranes, beads, fiber, glass wool, filter paper, polymers, and gel.
71. The method of claim 54, wherein the capture region comprises an extraction chamber formed in a microfluidic chip, and wherein the capture material comprises an array of microstructures extending into the extraction chamber, each of the microstructures having an aspect ratio (height to width) of at least 2:1.
72. The method of claim 54, wherein the capture region comprises a channel or chamber containing the capture material, and wherein the analyte is eluted from the capture region by heating the channel or chamber containing the capture material while forcing elution fluid to flow through the channel or chamber.
73. The method of claim 54, wherein the lysate is forced to recirculate through the capture region.
74. The method of claim 54, wherein the cartridge has a first flow path that includes the lysing and capture regions, the first flow path leading to a waste chamber, the cartridge has an elution flow path passing through the capture region and diverging from the first flow path, the lysate is forced to flow through the capture region and into the waste chamber via the first flow path, and the elution fluid is forced to flow through the capture region and along the diverging elution flow path.
75. The method of claim 54, wherein the analyte is eluted from the capture region by forcing elution fluid to flow through the capture region, and wherein the volume of sample forced to flow through the lysing region is greater than the volume of

SubB1) elution fluid forced to flow through the capture region, whereby the analyte extracted from the sample is concentrated in the smaller volume of elution fluid.

76. The method of claim 54, wherein the lysing region comprises a lysing chamber containing the solid phase material, and wherein the volume of sample forced to flow through the lysing chamber is greater than the volume capacity of the lysing chamber.

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78. The method of claim 54, wherein the volume of sample forced to flow through the lysing region is at least 1 ml.

79. The method of claim 54, wherein the capture region comprises an extraction chamber containing the capture material, and wherein the volume of lysate forced to flow through the extraction chamber is greater than the volume capacity of the extraction chamber.

80. The method of claim 79, wherein the ratio of the volume of lysate forced to flow through the extraction chamber to the volume capacity of the extraction chamber is at least 2:1.

81. A method for extracting nucleic acid from a fluid sample and for amplifying the nucleic acid, the method comprising the steps of:
a) introducing the sample into a cartridge having:
i) a lysing region for lysing sample components to release the nucleic acid therefrom;

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- ii) a capture region, the capture region comprising a channel or chamber containing capture material for capturing the nucleic acid;
- iii) at least one waste chamber; and
- iv) a reaction chamber for amplifying the nucleic acid;
- b) lysing the sample components in the lysing region to produce a lysate containing the nucleic acid;
- c) forcing the lysate to flow through the capture region, thereby capturing the nucleic acid with the capture material;
- d) forcing the lysate that has flowed through the capture region to flow into the waste chamber;
- e) forcing an elution fluid to flow through the capture region to elute the captured nucleic acid from the capture region;
- f) forcing the eluted nucleic acid to flow into the reaction chamber; and
- g) amplifying the nucleic acid in the reaction chamber.

82. The method of claim 81, further comprising the step of detecting the amplified nucleic acid in the reaction chamber.

83. The method of claim 81, wherein the portion of the cartridge defining the reaction chamber protrudes from the rest of the cartridge body, and wherein the temperature of the reaction chamber is controlled by inserting the reaction chamber into a thermal sleeve and heating or cooling the reaction chamber according to a time/temperature profile.

84. The method of claim 81, wherein the cartridge further includes a reagent chamber containing dried or lyophilized reagents, and the method further comprises the step of mixing the eluted nucleic acid with the reagents in the reagent chamber prior to forcing the nucleic acid to flow into the reaction chamber.

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85. The method of claim 81, wherein the lysing region comprises a lysing chamber containing solid phase material for capturing the sample components, and the method further comprises the step of forcing the sample to flow through the lysing chamber and into the at least one waste chamber, thereby capturing the sample components with the solid phase material in the lysing chamber.
86. The method of claim 85, wherein the step of lysing the sample components comprises transferring ultrasonic energy to the lysing chamber using an ultrasonic transducer coupled to a wall of the lysing chamber.
87. The method of claim 86, wherein the solid phase material comprises at least one membrane or filter for capturing the sample components, and wherein the step of lysing the sample components further comprises agitating particles or beads in the lysing chamber to rupture the sample components.
88. The method of claim 86, wherein the step of lysing the sample components further comprises placing a lysis buffer in the lysing chamber, the lysis buffer containing a lysing reagent.
89. The method of claim 86, wherein the transducer comprises an ultrasonic horn for contacting the wall of the lysing chamber.
90. The method of claim 85, wherein the volume of sample forced to flow through the lysing chamber is greater than the volume of elution fluid forced to flow through the capture region, whereby the nucleic acid extracted from the sample is concentrated in the smaller volume of elution fluid.
91. The method of claim 85, wherein the volume of sample forced to flow through the lysing chamber is greater than the volume capacity of the lysing chamber.

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92. The method of claim 85, wherein the ratio of the volume of sample forced to flow through the lysing chamber to the volume capacity of the lysing chamber is at least 2:1.
93. The method of claim 85, wherein the volume of sample forced to flow through the lysing chamber is at least 1 ml.
94. The method of claim 81, wherein the volume of lysate forced to flow through the capture region is greater than the volume capacity of the capture region.
95. The method of claim 81, wherein the ratio of the volume of lysate forced to flow through the capture region to the volume capacity of the capture region is at least 2:1.
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96. The method of claim 81, wherein the capture material comprises at least one solid support selected from the group consisting of filters, membranes, beads, fiber, glass wool, filter paper, polymers, and gel.
97. The method of claim 81, wherein the capture region comprises an extraction chamber formed in a microfluidic chip, and wherein the capture material comprises an array of microstructures extending into the extraction chamber, each of the microstructures having an aspect ratio (height to width) of at least 2:1.
98. The method of claim 81, further comprising the step of heating the capture region while forcing the elution fluid to flow through the capture region.

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99. A method for separating nucleic acid from a fluid sample and for amplifying the nucleic acid, the method comprising the steps of:
- a) introducing the sample into a cartridge having:
 - i) a lysing region for lysing sample components to release the nucleic acid therefrom;
 - ii) a capture region comprising a channel or chamber containing capture material for capturing the nucleic acid; and
 - iii) at least one waste chamber;
 - b) lysing the sample components in the lysing region to produce a lysate containing the nucleic acid;
 - c) forcing the lysate to flow through the capture region, thereby capturing the nucleic acid with the capture material in the capture region;
 - d) forcing the lysate that has flowed through the capture region to flow into the waste chamber;
 - e) forcing an elution fluid to flow through the capture region to elute the captured nucleic acid from the capture region;
 - f) forcing the eluted nucleic acid to flow into a reaction vessel coupled to the cartridge; and
 - g) amplifying the nucleic acid in the reaction vessel.
100. The method of claim 99, further comprising the step of detecting the amplified nucleic acid in the reaction vessel.
101. The method of claim 99, wherein the temperature of the reaction vessel is controlled by inserting the vessel into a thermal sleeve and heating or cooling the vessel according to a time/temperature profile.
102. The method of claim 99, wherein the cartridge further includes a reagent chamber containing dried or lyophilized reagents, and the method further comprises the

step of mixing the eluted nucleic acid with the reagents in the reagent chamber prior to forcing the nucleic acid to flow into the reaction vessel.

103. The method of claim 99, wherein the lysing region comprises a lysing chamber containing solid phase material for capturing the sample components, and the method further comprises the step of forcing the sample to flow through the lysing chamber and into the at least one waste chamber, thereby capturing the sample components with the solid phase material in the lysing chamber.
104. The method of claim 103, wherein the step of lysing the sample components comprises transferring ultrasonic energy to the lysing chamber using an ultrasonic transducer coupled to a wall of the lysing chamber.
105. The method of claim 104, wherein the solid phase material comprises at least one membrane or filter for capturing the sample components, and wherein the step of lysing the sample components further comprises agitating particles or beads in the lysing chamber to rupture the sample components.
106. The method of claim 104, wherein the step of lysing the sample components further comprises placing a lysis buffer in the lysing chamber, the lysis buffer containing a lysing reagent.
107. The method of claim 104, wherein the transducer comprises an ultrasonic horn for contacting the wall of the lysing chamber.
108. The method of claim 103, wherein the volume of sample forced to flow through the lysing chamber is greater than the volume of elution fluid forced to flow through the capture region, whereby the nucleic acid extracted from the sample is concentrated in the smaller volume of elution fluid.

109. The method of claim 103, wherein the volume of sample forced to flow through the lysing chamber is greater than the volume capacity of the lysing chamber.
110. The method of claim 103, wherein the ratio of the volume of sample forced to flow through the lysing chamber to the volume capacity of the lysing chamber is at least 2:1.
111. The method of claim 103, wherein the volume of sample forced to flow through the lysing chamber is at least 1 ml.
112. The method of claim 99, wherein the volume of lysate forced to flow through the capture region is greater than the volume capacity of the capture region.
113. The method of claim 99, wherein the ratio of the volume of lysate forced to flow through the capture region to the volume capacity of the capture region is at least 2:1.
114. The method of claim 99, wherein the capture material comprises at least one solid support selected from the group consisting of filters, membranes, beads, fiber, glass wool, filter paper, polymers, and gel.
115. The method of claim 99, wherein the capture region comprises an extraction chamber formed in a microfluidic chip, and wherein the capture material comprises an array of microstructures extending into the extraction chamber, each of the microstructures having an aspect ratio (height to width) of at least 2:1.
116. The method of claim 99, further comprising the step of heating the capture region while forcing the elution fluid to flow through the capture region.

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117. A method for separating nucleic acid from a fluid sample and for amplifying the nucleic acid, the method comprising the steps of:
- a) introducing the sample into a cartridge having:
 - i) a capture region, the capture region comprising a channel or chamber containing capture material for capturing the nucleic acid; and
 - ii) a waste chamber for receiving waste fluid from the capture region;
 - b) forcing the sample to flow through the capture region, thereby extracting the nucleic acid from the sample with the capture material in the capture region;
 - c) forcing the remaining sample fluid that has flowed through the capture region to flow into the waste chamber;
 - d) forcing an elution fluid to flow through the capture region to elute the captured nucleic acid from the capture region;
 - e) forcing the eluted nucleic acid to flow into a reaction vessel coupled to the cartridge; and
 - f) amplifying the nucleic acid in the reaction vessel.
118. The method of claim 117, further comprising the step of detecting the amplified nucleic acid in the reaction vessel.
119. The method of claim 117, wherein the temperature of the reaction vessel is controlled by inserting the vessel into a thermal sleeve and heating or cooling the vessel according to a predetermined time/temperature profile.
120. The method of claim 117, wherein the cartridge further includes a reagent chamber containing dried or lyophilized reagents, and the method further comprises the step of mixing the eluted nucleic acid with the reagents in the reagent chamber prior to forcing the nucleic acid to flow into the reaction vessel.

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121. The method of claim 117, wherein the volume of sample forced to flow through the capture region is greater than the volume of elution fluid forced to flow through the capture region, whereby the nucleic acid extracted from the sample is concentrated in the smaller volume of elution fluid.
122. The method of claim 117, wherein the ratio of the volume of sample forced to flow through the capture region to the volume capacity of the capture region is at least 2:1.
123. The method of claim 117, wherein the volume of sample forced to flow through the capture region is at least 1 ml.
124. The method of claim 117, wherein the capture material comprises at least one solid support selected from the group consisting of filters, membranes, beads, fiber, glass wool, filter paper, polymers, and gel.
125. The method of claim 117, wherein the capture region comprises an extraction chamber formed in a microfluidic chip, and wherein the capture material comprises an array of microstructures extending into the extraction chamber, each of the microstructures having an aspect ratio (height to width) of at least 2:1.
126. A method for separating nucleic acid from a fluid sample and for amplifying the nucleic acid, the method comprising the steps of:
- a) introducing the sample into a cartridge having:
 - i) a flow path through a capture region, the capture region comprising a channel or chamber containing capture material for capturing the nucleic acid;
 - ii) a waste chamber for receiving waste fluid from the capture region;

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- iii) a reaction chamber for amplifying the nucleic acid;
 - b) forcing the sample to flow through the capture region, thereby capturing the nucleic acid with the capture material;
 - c) forcing the remaining sample fluid that has flowed through the capture region to flow into the waste chamber;
 - d) forcing an elution fluid to flow through the capture region to elute the captured nucleic acid from the capture region;
 - e) forcing the eluted nucleic acid to flow into the reaction chamber; and
 - f) amplifying the nucleic acid in the reaction chamber.

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127. The method of claim 126, further comprising the step of detecting the amplified nucleic acid in the reaction vessel.

128. The method of claim 126, wherein the portion of the cartridge defining the reaction chamber protrudes from the rest of the cartridge body, and wherein the temperature of the reaction chamber is controlled by inserting the reaction chamber into a thermal sleeve and heating or cooling the reaction chamber according to a time/temperature profile.

129. The method of claim 126, wherein the cartridge further includes a reagent chamber containing dried or lyophilized reagents, and the method further comprises the step of mixing the eluted nucleic acid with the reagents in the reagent chamber prior to forcing the nucleic acid to flow into the reaction chamber.

130. The method of claim 126, wherein the volume of sample forced to flow through the capture region is greater than the volume of elution fluid forced to flow

through the capture region, whereby the nucleic acid extracted from the sample is concentrated in the smaller volume of elution fluid.

131. The method of claim 126, wherein the volume of sample forced to flow through the capture region is greater than the volume capacity of the capture region.
132. The method of claim 126, wherein the ratio of the volume of sample forced to flow through the capture region to the volume capacity of the capture region is at least 2:1.
133. The method of claim 126, wherein the volume of sample forced to flow through the capture region is at least 1 ml.
134. The method of claim 126, wherein the capture material comprises at least one solid support selected from the group consisting of filters, membranes, beads, fiber, glass wool, filter paper, polymers, and gel.
135. The method of claim 126, wherein the capture region comprises an extraction chamber formed in a microfluidic chip, and wherein the capture material comprises an array of microstructures extending into the extraction chamber, each of the microstructures having an aspect ratio (height to width) of at least 2:1.
136. The method of claim 126, further comprising the step of heating the capture region while forcing the elution fluid to flow through the capture region.
137. A method for extracting nucleic acid from a sample, the sample containing cells, spores, or microorganisms, the method comprising the steps of:
- a) introducing the sample into a cartridge having:
 - i) a lysing region for lysing the cells, spores, or microorganisms to

release the nucleic acid therefrom; and

- ii) at least one waste chamber;
- b) contacting the sample with paper or membrane material in the lysing region, the paper or membrane material being impregnated with at least one chemical for lysing the cells, spores, or microorganisms in the sample;
- c) lysing the cells, spores, or microorganisms with the at least one chemical;
- d) binding the nucleic acid released from the cells, spores, or microorganisms to the paper or membrane material;
- e) washing the lysing region with wash fluid and forcing the wash fluid to flow from the lysing region into the at least one waste chamber while the nucleic acid remains bound to the paper or membrane material in the lysing region; and
- f) eluting the nucleic acid from the paper or membrane material.

138. The method of claim 137, wherein the cartridge further includes a reaction chamber, and the method further comprises the steps of:

- i) forcing the eluted nucleic acid to flow into the reaction chamber;
- ii) amplifying the nucleic acid in the reaction chamber; and
- iii) detecting the amplified nucleic acid.

139. The method of claim 138, wherein the amplification requires temperature control of the reaction chamber, the portion of the cartridge defining the reaction chamber protrudes from the rest of the cartridge body, and the temperature of the reaction chamber is controlled by inserting the reaction chamber into a thermal sleeve and heating or cooling the reaction chamber according to a time/temperature profile.

140. The method of claim 138, wherein the cartridge further includes a reagent chamber containing dried or lyophilized reagents, and the method further comprises the step of mixing the eluted nucleic acid with the reagents in the

reagent chamber prior to forcing the nucleic acid to flow into the reaction chamber.

141. The method of claim 137, further comprising the steps of:
- i) forcing the eluted nucleic acid to flow into a reaction vessel coupled to the cartridge;
 - ii) amplifying the nucleic acid in the reaction vessel; and
 - iii) detecting the amplified nucleic acid.
142. The method of claim 141, wherein the amplification requires temperature control of the reaction vessel, and wherein the temperature of the vessel is controlled by inserting the vessel into a thermal sleeve and heating or cooling the vessel according to a time/temperature profile.
143. The method of claim 141, wherein the cartridge further includes a reagent chamber containing dried or lyophilized reagents, and the method further comprises the step of mixing the eluted nucleic acid with the reagents in the reagent chamber prior to forcing the nucleic acid to flow into the reaction vessel.
144. The method of claim 137, wherein:
- a) the cartridge further includes a capture region, the capture region comprising a channel or chamber containing capture material for capturing the nucleic acid;
 - b) the nucleic acid is eluted from the paper or membrane material by placing fluid into the lysing region and releasing the nucleic acid from the paper or membrane material into the fluid;
 - c) and the method further comprises the steps of concentrating the nucleic acid by:

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- i) forcing the fluid containing the nucleic acid to flow out of the lysing region and through the capture region to capture the nucleic acid with the capture material;
- ii) forcing the fluid that has flowed through the capture region to flow into at least one waste chamber in the cartridge; and
- iii) eluting the nucleic acid from the capture region.

145. The method of claim 144, wherein the capture material comprises at least one solid support selected from the group consisting of filters, membranes, beads, fiber, glass wool, filter paper, polymers, and gel.
146. The method of claim 144, wherein the capture region comprises an extraction chamber formed in a microfluidic chip, and wherein the capture material comprises an array of microstructures extending into the extraction chamber, each of the microstructures having an aspect ratio (height to width) of at least 2:1.
147. The method of claim 144, wherein the cartridge has a first flow path that includes the lysing and capture regions, the first flow path leading to the at least one waste chamber, the cartridge has an elution flow path passing through the capture region and diverging from the first flow path, the elution flow path leading to an additional chamber in the cartridge for receiving the nucleic acid, the fluid containing the nucleic acid is forced to flow through the capture region and into the at least one waste chamber via the first flow path, thereby separating the nucleic acid from the fluid in the capture region, and the nucleic acid is eluted from the capture region by forcing elution fluid to flow through the capture region and into the additional chamber via the diverging elution flow path.
148. The method of claim 144, wherein the cartridge further includes a reaction chamber, and the method further comprises the step of forcing the nucleic acid

eluted from the capture region to flow into the reaction chamber and amplifying the nucleic acid in the reaction chamber.

149. The method of claim 144, further comprising the step of forcing the nucleic acid eluted from the capture region to flow into a reaction vessel coupled to the cartridge and amplifying the nucleic acid in the reaction vessel.
150. The method of claim 144, wherein the cartridge has a first flow path that includes the lysing and capture regions, the first flow path leading to the at least one waste chamber, the cartridge has an elution flow path passing through the capture region and diverging from the first flow path, a reaction vessel is coupled to the cartridge for receiving the nucleic acid eluted from the capture region via the elution flow path, the fluid containing the nucleic acid is forced to flow through the capture region and into the at least one waste chamber via the first flow path, thereby separating the nucleic acid from the fluid in the capture region, the nucleic acid is eluted from the capture region by forcing elution fluid to flow through the capture region and along the diverging elution flow path, the nucleic acid eluted from the capture region is forced to flow into the reaction vessel, and the nucleic acid is amplified in the reaction vessel.
151. The method of claim 137, wherein the step of lysing the cells, spores, or microorganisms with the at least one chemical comprises drying the sample on the paper or membrane material by heating or desiccation.
152. The method of claim 151, wherein the cartridge further includes a desiccant adjacent the lysing region, and wherein the sample is dried on the paper or membrane material by heating the sample and absorbing moisture with the desiccant.

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153. The method of claim 151, wherein the nucleic acid is eluted from the paper or membrane material by placing fluid in the lysing region, heating the lysing region to release the nucleic acid from the paper or membrane material into the fluid, and forcing the fluid containing the nucleic acid to flow out of the lysing region.
154. The method of claim 153, further comprising the step binding contaminants or inhibitors to the paper or membrane material prior to releasing the nucleic acid from the paper or membrane material into the fluid, and wherein the contaminants or inhibitors remain bound to the paper or membrane material while the nucleic acid is eluted from the paper or membrane material.
155. The method of claim 137, wherein the chemical comprises at least one lysing agent selected from the group consisting of enzymes, detergents, and chaotropes.
156. The method of claim 137, wherein the chemical comprises a chaotropic salt.
157. The method of claim 137, wherein the paper or membrane material comprises cellulose, nitrocellulose, polycarbonate, or nylon.
158. A method for extracting nucleic acid from a sample, the sample containing cells, spores, or microorganisms, the method comprising the steps of:
- a) introducing the sample into a cartridge having:
 - i) a lysing region for lysing the cells, spores, or microorganisms to release the nucleic acid therefrom; and
 - ii) a capture region, the capture region comprising a channel or chamber containing capture material for capturing the nucleic acid;
 - b) drying the sample on paper or membrane material in the lysing region, the paper or membrane material being impregnated with at least one chemical for lysing the cells, spores, or microorganisms in the sample;

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- c) lysing the cells, spores, or microorganisms with the chemical to release the nucleic acid from the cells, spores, or microorganisms;
- d) binding contaminants or inhibitors in the sample to the paper or membrane material;
- e) placing fluid in the lysing region and releasing the nucleic acid from the paper or membrane material into the fluid while the contaminants or inhibitors remain bound to the paper or membrane material;
- f) forcing the fluid containing the nucleic acid to flow through the capture region to capture the nucleic acid with the capture material; and
- g) eluting the nucleic acid from the capture region.

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- i) forcing the nucleic acid eluted from the capture region to flow into the reaction chamber;
- ii) amplifying the nucleic acid in the reaction chamber; and
- iii) detecting the amplified nucleic acid.

160. The method of claim 159, wherein the amplification requires temperature control of the reaction chamber, the portion of the cartridge defining the reaction chamber protrudes from the rest of the cartridge body, and the temperature of the reaction chamber is controlled by inserting the reaction chamber into a thermal sleeve and heating or cooling the reaction chamber according to a time/temperature profile.

161. The method of claim 160, wherein the cartridge further includes a reagent chamber containing dried or lyophilized reagents, and the method further comprises the step of mixing the nucleic acid with the reagents in the reagent chamber prior to forcing the nucleic acid to flow into the reaction chamber.

162. The method of claim 158, further comprising the steps of:
- i) forcing the nucleic acid eluted from the capture region to flow into a reaction vessel coupled to the cartridge;
 - ii) amplifying the nucleic acid in the reaction vessel; and
 - iii) detecting the amplified nucleic acid.
163. The method of claim 162, wherein the amplification requires temperature control of the reaction vessel, and wherein the temperature of the vessel is controlled by inserting the vessel into a thermal sleeve and heating or cooling the vessel according to a time/temperature profile.
164. The method of claim 162, wherein the cartridge further includes a reagent chamber containing dried or lyophilized reagents, and the method further comprises the step of mixing the eluted nucleic acid with the reagents in the reagent chamber prior to forcing the nucleic acid to flow into the reaction vessel.
165. The method of claim 158, wherein the capture material comprises at least one solid support selected from the group consisting of filters, membranes, beads, fiber, glass wool, filter paper, polymers, and gel.
166. The method of claim 158, wherein the capture region comprises an extraction chamber formed in a microfluidic chip, and wherein the capture material comprises an array of microstructures extending into the extraction chamber, each of the microstructures having an aspect ratio (height to width) of at least 2:1.
167. The method of claim 158, wherein the cartridge includes at least one waste chamber for receiving waste fluid and at least one additional chamber for receiving the nucleic acid eluted from the capture region, the fluid forced to flow through the capture region in step (f) is forced to flow into the at least one waste

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chamber after flowing through the capture region, and the nucleic acid is eluted from the capture region by forcing elution fluid to flow through the capture region and into the additional chamber.

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168. The method of claim 167, wherein the volume of sample placed in the lysing region is greater than the volume of elution fluid forced to flow through the capture region, whereby the nucleic acid extracted from the sample is concentrated in the smaller volume of elution fluid.
169. The method of claim 167, wherein the ratio of the volume of fluid forced to flow through the capture region in step (f) to the volume capacity of the capture region is at least 2:1.
170. The method of claim 167, wherein the additional chamber comprises a reagent chamber containing reagents, and the method further comprises the step of mixing the nucleic acid with the reagents in the reagent chamber.
171. The method of claim 167, wherein the additional chamber comprises a reaction chamber, and the method further comprises the step of amplifying the nucleic acid in the reaction chamber.
172. The method of claim 158, wherein the cartridge includes at least one waste chamber for receiving waste fluid, the fluid forced to flow through the capture region in step (f) is forced to flow into the at least one waste chamber after flowing through the capture region, and the nucleic acid is eluted from the capture region by forcing elution fluid to flow through the capture region and into a reaction vessel coupled to the cartridge.

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173. The method of claim 172, wherein the volume of sample placed in the lysing region is greater than the volume of elution fluid forced to flow through the capture region, whereby the nucleic acid extracted from the sample is concentrated in the smaller volume of elution fluid.
174. The method of claim 172, wherein the ratio of the volume of fluid forced to flow through the capture region in step (f) to the volume capacity of the capture region is at least 2:1.
175. The method of claim 172, wherein the cartridge includes a reagent chamber, and the method further comprises the step of mixing the nucleic acid eluted from the capture region with reagents in the reagent chamber prior to forcing the nucleic acid to flow into the reaction vessel.
176. The method of claim 172, further comprising the step of amplifying and detecting the nucleic acid in the reaction vessel.
177. The method of claim 158, wherein the cartridge includes a desiccant adjacent the lysing region, and wherein the sample is dried on the paper or membrane material by heating the sample and absorbing moisture with the desiccant.
178. The method of claim 158, wherein the nucleic acid is released from the paper or membrane material into the fluid in the lysing region by heating the paper or membrane material.
179. The method of claim 158, wherein the cartridge includes at least one waste chamber, and wherein step (e) is preceded by the additional steps of binding the nucleic acid released from the cells, spores, or microorganisms to the paper or membrane material, washing the lysing region with wash fluid, and forcing the

wash fluid to flow out of the lysing region and into the at least one waste chamber while the nucleic acid remains bound to the paper or membrane material.

180. The method of claim 158, wherein the chemical comprises at least one lysing agent selected from the group consisting of enzymes, detergents, and chaotropes.

181. The method of claim 158, wherein the chemical comprises a chaotropic salt.

182. The method of claim 158, wherein the paper or membrane material comprises cellulose, nitrocellulose, polycarbonate, or nylon.

A4 183. A method for extracting nucleic acid from a sample, the sample containing cells, spores, or microorganisms, the method comprising the steps of:

- a) introducing the sample into a cartridge having:
 - i) a lysing chamber for lysing the cells, spores, or microorganisms to release the nucleic acid therefrom;
 - ii) a capture region containing capture material for capturing the nucleic acid;
 - iii) at least one waste chamber; and
 - iv) at least a third chamber for receiving the nucleic acid extracted from the sample;
- b) contacting the sample with paper or membrane material in the lysing chamber, the paper or membrane material being impregnated with at least one chemical for lysing the cells, spores, or microorganisms in the sample;
- c) lysing the cells, spores, or microorganisms with the chemical to release the nucleic acid from the cells, spores, or microorganisms;
- d) removing the nucleic acid from the lysing chamber by placing fluid in the lysing chamber, releasing the nucleic acid from the paper or membrane material into the fluid, and forcing the fluid containing the nucleic acid to

flow out of the lysing chamber and through the capture region, thereby capturing the nucleic acid from the fluid with the capture material in the capture region;

- e) forcing the fluid that has flowed through the capture region to flow into the waste chamber; and
- f) eluting the captured nucleic acid from the capture region and forcing the eluted nucleic acid to flow into the third chamber.

184. The method of claim 183, the third chamber comprises a reaction chamber, and the method further comprises the steps of:

- i) amplifying the nucleic acid in the reaction chamber; and
- ii) detecting the amplified nucleic acid.

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185. The method of claim 184, wherein the amplification requires temperature control of the reaction chamber, the portion of the cartridge defining the reaction chamber protrudes from the rest of the cartridge body, and the temperature of the reaction chamber is controlled by inserting the reaction chamber into a thermal sleeve and heating or cooling the reaction chamber according to a time/temperature profile.

186. The method of claim 184, wherein the cartridge further includes a reagent chamber containing dried or lyophilized reagents, and the method further comprises the step of mixing the eluted nucleic acid with the reagents in the reagent chamber prior to forcing the nucleic acid to flow into the reaction chamber.

187. The method of claim 183, wherein the capture material comprises at least one solid support selected from the group consisting of filters, membranes, beads, fiber, glass wool, filter paper, polymers, and gel.

188. The method of claim 183, wherein the capture region comprises an extraction chamber formed in a microfluidic chip, and wherein the capture material comprises an array of microstructures extending into the extraction chamber, each of the microstructures having an aspect ratio (height to width) of at least 2:1.
189. The method of claim 183, wherein the captured nucleic acid is eluted from the capture region by forcing elution fluid to flow through the capture region, and wherein the volume of sample placed in the lysing chamber is greater than the volume of elution fluid forced to flow through the capture region, whereby the nucleic acid extracted from the sample is concentrated in the smaller volume of elution fluid.
- A 4 190. The method of claim 183, wherein the ratio of the volume of fluid forced to flow through the capture region in step (d) to the volume capacity of the capture region is at least 2:1.
191. The method of claim 183, wherein the step of lysing the cells, spores, or microorganisms with the at least one chemical comprises drying the sample on the paper or membrane material by heating or desiccation.
192. The method of claim 191, wherein the cartridge further includes a desiccant adjacent the lysing chamber, and wherein the sample is dried on the paper or membrane material by heating the sample and absorbing moisture with the desiccant.
193. The method of claim 183, wherein the nucleic acid is released from the paper or membrane material into the fluid in the lysing chamber by heating the paper or membrane material.

194. The method of claim 183, wherein step (d) is preceded by the additional steps of binding the nucleic acid released from the cells, spores, or microorganisms to the paper or membrane material, washing the lysing chamber with wash fluid, and forcing the wash fluid to flow out of the lysing chamber and into the at least one waste chamber while the nucleic acid remains bound to the paper or membrane material.
195. The method of claim 183, wherein step (d) is preceded by the additional step of binding contaminants or inhibitors in the sample to the paper or membrane material, and wherein the contaminants or inhibitors remain bound to the paper or membrane material while the nucleic acid is removed from the lysing chamber.
- A 4 196. The method of claim 183, wherein the chemical comprises at least one lysing agent selected from the group consisting of enzymes, detergents, and chaotropes.
197. The method of claim 183, wherein the chemical comprises a chaotropic salt.
198. The method of claim 183, wherein the paper or membrane material comprises cellulose, nitrocellulose, polycarbonate, or nylon.
199. A method for extracting nucleic acid from a sample, the sample containing cells, spores, or microorganisms, the method comprising the steps of:
- a) introducing the sample into a cartridge having:
 - i) a lysing chamber for lysing the cells, spores, or microorganisms to release the nucleic acid therefrom;
 - ii) a capture region, the capture region comprising a channel or chamber containing capture material for capturing the nucleic acid; and
 - iii) at least one waste chamber;

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- b) contacting the sample with paper or membrane material in the lysing chamber, the paper or membrane material being impregnated with at least one chemical for lysing the cells, spores, or microorganisms in the sample;
 - c) lysing the cells, spores, or microorganisms with the chemical to release the nucleic acid from the cells, spores, or microorganisms;
 - d) removing the nucleic acid from the lysing chamber by placing fluid in the lysing chamber, releasing the nucleic acid from the paper or membrane material into the fluid, and forcing the fluid containing the nucleic acid to flow out of the lysing chamber and through the capture region, thereby capturing the nucleic acid from the fluid with the capture material in the capture region;
 - e) forcing the fluid that has flowed through the capture region to flow into the waste chamber; and
 - f) eluting the captured nucleic acid from the capture region and forcing the eluted nucleic acid to flow into a reaction vessel coupled to the cartridge.

200. The method of claim 199, further comprising the steps of:

- i) amplifying the nucleic acid in the reaction vessel; and
- ii) detecting the amplified nucleic acid.

201. The method of claim 200, wherein the amplification requires temperature control of the reaction vessel, and wherein the temperature of the vessel is controlled by inserting the vessel into a thermal sleeve and heating or cooling the vessel according to a time/temperature profile.

202. The method of claim 200, wherein the cartridge further includes a reagent chamber containing dried or lyophilized reagents, and the method further comprises the step of mixing the nucleic acid eluted from the capture region with

the reagents in the reagent chamber prior to forcing the nucleic acid to flow into the reaction vessel.

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203. The method of claim 199, wherein the capture material comprises at least one solid support selected from the group consisting of filters, membranes, beads, fiber, glass wool, filter paper, polymers, and gel.
204. The method of claim 199, wherein the capture region comprises an extraction chamber formed in a microfluidic chip, and wherein the capture material comprises an array of microstructures extending into the extraction chamber, each of the microstructures having an aspect ratio (height to width) of at least 2:1.
205. The method of claim 199, wherein the captured nucleic acid is eluted from the capture region by forcing elution fluid to flow through the capture region, and wherein the volume of sample placed in the lysing chamber is greater than the volume of elution fluid forced to flow through the capture region, whereby the nucleic acid extracted from the sample is concentrated in the smaller volume of elution fluid.
206. The method of claim 199, wherein the ratio of the volume of fluid forced to flow through the capture region in step (d) to the volume capacity of the capture region is at least 2:1.
207. The method of claim 199, wherein the step of lysing the cells, spores, or microorganisms with the at least one chemical comprises drying the sample on the paper or membrane material by heating or desiccation.
208. The method of claim 207, wherein the cartridge further includes a desiccant adjacent the lysing chamber, and wherein the sample is dried on the paper or

membrane material by heating the sample and absorbing moisture with the desiccant.

209. The method of claim 199, wherein the nucleic acid is released from the paper or membrane material into the fluid in the lysing chamber by heating the paper or membrane material.
210. The method of claim 199, wherein step (d) is preceded by the additional steps of binding the nucleic acid released from the cells, spores, or microorganisms to the paper or membrane material, washing the lysing chamber with wash fluid, and forcing the wash fluid to flow out of the lysing chamber and into the at least one waste chamber while the nucleic acid remains bound to the paper or membrane material.
211. The method of claim 199, wherein step (d) is preceded by the additional step of binding contaminants or inhibitors in the sample to the paper or membrane material, and wherein the contaminants or inhibitors remain bound to the paper or membrane material while the nucleic acid is removed from the lysing chamber.
212. The method of claim 199, wherein the chemical comprises at least one lysing agent selected from the group consisting of enzymes, detergents, and chaotropes.
213. The method of claim 199, wherein the chemical comprises a chaotropic salt.
214. The method of claim 199, wherein the paper or membrane material comprises cellulose, nitrocellulose, polycarbonate, or nylon.
215. A method for separating an analyte from a fluid sample, the method comprising the steps of:

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- a) introducing the sample into a cartridge having:
 - i) a lysing region for lysing sample components to release the analyte therefrom; and
 - ii) a flow-through microfluidic chip for capturing the analyte, the microfluidic chip comprising a body having an extraction chamber and an array of microstructures extending into the extraction chamber for capturing the analyte, wherein each of the microstructures has an aspect ratio (height to width) of at least 2:1;
 - b) lysing the sample components in the lysing region;
 - c) forcing the lysed sample to flow through the extraction chamber and out of the microfluidic chip, thereby capturing the analyte with the microstructures in the extraction chamber;
 - d) eluting the captured analyte from the microfluidic chip by forcing an elution fluid to flow through the extraction chamber and out of the microfluidic chip.

216. The method of claim 215, wherein the cartridge further includes a reaction chamber, and the method further comprises the steps of:

- i) forcing the eluted analyte to flow into the reaction chamber;
- ii) chemically reacting the analyte in the reaction chamber; and
- iii) detecting a reaction product.

217. The method of claim 216, wherein the analyte comprises nucleic acid, and wherein the steps of chemically reacting the analyte and detecting the reaction product comprise amplifying the nucleic acid and detecting the amplified nucleic acid.

218. The method of claim 216, wherein the cartridge further includes a reagent chamber containing dried or lyophilized reagents, and the method further

comprises the step of mixing the nucleic acid with the reagents in the reagent chamber prior to forcing the nucleic acid to flow into the reaction chamber.

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219. The method of claim 215, further comprising the steps of:
- i) forcing the eluted analyte to flow into a reaction vessel coupled to the cartridge;
 - ii) chemically reacting the analyte in the reaction vessel; and
 - iii) detecting a reaction product.
220. The method of claim 219, wherein the analyte comprises nucleic acid, and wherein the steps of chemically reacting the analyte and detecting the reaction product comprise amplifying the nucleic acid and detecting the amplified nucleic acid.
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221. The method of claim 219, wherein the cartridge further includes a reagent chamber containing dried or lyophilized reagents, and the method further comprises the step of mixing the eluted nucleic acid with the reagents in the reagent chamber prior to forcing the nucleic acid to flow into the reaction vessel.
222. The method of claim 215, wherein the step of lysing the sample components comprises transferring ultrasonic energy to the lysing region using an ultrasonic transducer coupled to a wall of the lysing region.
223. The method of claim 215, wherein the volume of sample forced to flow through the extraction chamber is greater than the volume of elution fluid forced to flow through the extraction chamber, whereby the analyte extracted from the sample is concentrated in the smaller volume of elution fluid.
224. The method of claim 215, wherein the volume of sample forced to flow through

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the extraction chamber is greater than the volume capacity of the extraction chamber.

225. The method of claim 215, wherein the ratio of the volume of sample forced to flow through the extraction chamber to the volume capacity of the extraction chamber is at least 2:1.

226. The method of claim 215, wherein the volume of sample forced to flow through the extraction chamber is at least 1 ml.

REMARKS

Applicant has deleted non-critical text from the specification.

Entry of new claims 54-226 is earnestly solicited. No new matter is introduced thereby.

Respectfully submitted,



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